

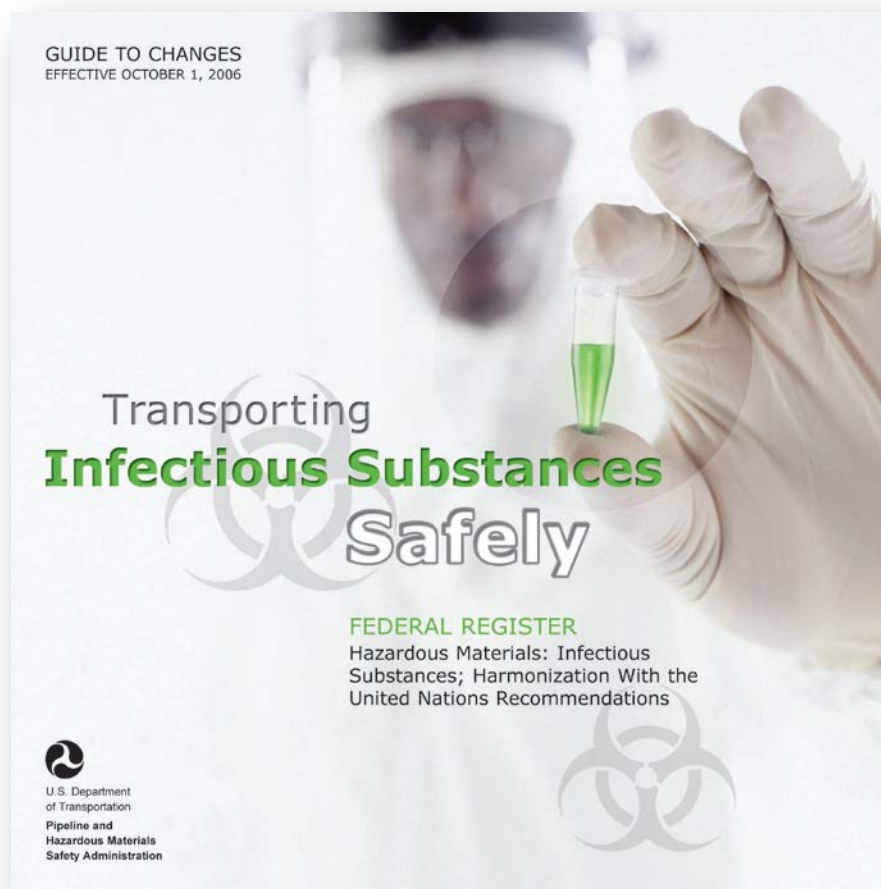


Transporting Infectious Substances Safely





Infectious Substances Guide





Objective

- Provide a general overview of the regulatory requirements for transporting Division 6.2 materials:
 - Definitions and Package Selection
 - Marking and Labeling
 - Shipping Papers and Emergency Response Information
 - Security and Training
- Identify requirements for Regulated Medical Waste





U.S. DOT Hazardous Materials Regulations (HMR)

The HMR govern the packaging and safe transportation of hazardous materials by air, highway, rail, and water (except bulk transportation onboard vessel)





Other Federal Regulations Governing Safe Transport of Infectious Substances

- Department of Health and Human Services (HHS)
42 CFR Parts 72 and 73 – Interstate Shipment of Etiologic Agents and Select Agents and Toxins
- Department of Labor/OSHA
29 CFR, Section 1910.1030 – Bloodborne Pathogens





International Regulations

- The International Civil Aviation Organization (ICAO)
 - ICAO Technical Instructions for the safe Transport of Dangerous Goods
- The International Maritime Organization (IMO)
 - International Maritime Dangerous Goods Code (IMDG Code)
- The HM226A Final Rule on Infectious Substances
 - Brought HMR in harmonization with international documents





HM226A Final Rule

- Hazardous Materials: Infectious Substances; Harmonization With United Nations Recommendations
 - Published: Federal Register Vol. 71, No. 106, June 2, 2006
 - Effective: October 1, 2006





Significant Changes

- New Classification System
 - Category A and Category B
 - *NO MORE RISK GROUPS*
- New and Revised Definitions
 - Modified Division 6.2 material
 - Modified Biological Product
 - Modified Regulated Medical Waste
 - Modified Culture
 - New Patient Specimen





Significant Changes (cont'd)

- Hazardous Materials Table Changes
 - Removed Diagnostic Specimen
 - Added Biological Substance Category B
- Security Plans
- Packing and Labeling
- Carriage by Aircraft





Division 6.2 Materials

- Infectious Substance
- Biological Product
- Cultures and Stocks
- Regulated Medical Waste





Infectious Substance Definition

- A material known or suspected to contain a pathogen:
 - a microorganism (including bacteria, viruses, parasites, fungi) or other agent, that can cause disease in humans or animals.
- Infectious substances must be assigned to one of four UN Identification numbers.





Category A Infectious Substance

- A form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposed
- Classification based on:
 - known medical history or symptoms of source patient or animal
 - endemic local conditions or professional judgment





Category A Infectious Substance

- Identified as:
 - Infectious substances, affecting animals *only*, UN2900; and
 - Infectious substances, affecting humans, UN2814





Category B Infectious Substance

- A form that is not generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposed
- Identified as:
 - Biological substance, Category B, UN3373





Biological Product Definition

- Virus, serum, toxin, antitoxin, vaccine, blood, blood component, allergenic product used in prevention, diagnosis, treatment of disease
- Includes materials manufactured in accordance with FDA, USDA regulations
- Excepted if subject to federal approval, permit or license requirements (FDA, USDA)





Biological Product Identification

- When known or expected to contain pathogens of Category A or Category B (unless excepted):
 - **Category A**
 - UN 2814
 - UN 2900
 - **Category B**
 - UN 3373





Culture Definition

- An infectious substance containing a pathogen that is intentionally propagated
- Does not include human or animal patient specimens





Patient Specimen Definition

- Human or animal material (excreta, secreta, blood, tissue, tissue swabs) transported for diagnostic or investigational purposes
- Transported as Category B infectious substances
 - not considered capable of causing permanent disability or life-threatening or fatal disease in healthy humans or animals if exposure occurs





Regulated Medical Waste Definition

- Waste or reusable material, *other than Category A*,
 - derived from medical treatment of humans or animals including diagnosis and immunization; or
 - from biomedical research
 - includes production and testing of biological products





Regulated Medical Waste Identification

- Contains or suspected to contain Category A substance
 - must be identified as a Category A infectious substance UN 2814 or UN 2900, as applicable.
- Contains Category B
 - identified as Regulated Medical Waste, UN 3291





Exceptions

- A material that is unlikely to cause disease in humans or animals
- Non-infectious biological materials from humans, animals, or plants
- A material containing neutralized or inactivated pathogens and no longer pose a health risk
- Blood collected for transfusion or preparation of blood products sent for testing (unless believed to contain an infectious substance)





Exceptions (cont'd)

- Laundry, medical equipment conforming to OSHA regs 29 CFR 1910.1030
- Any waste or recyclable material, other than RMW
- Corpses, remains, and anatomical parts intended for interment, cremation, or medical research





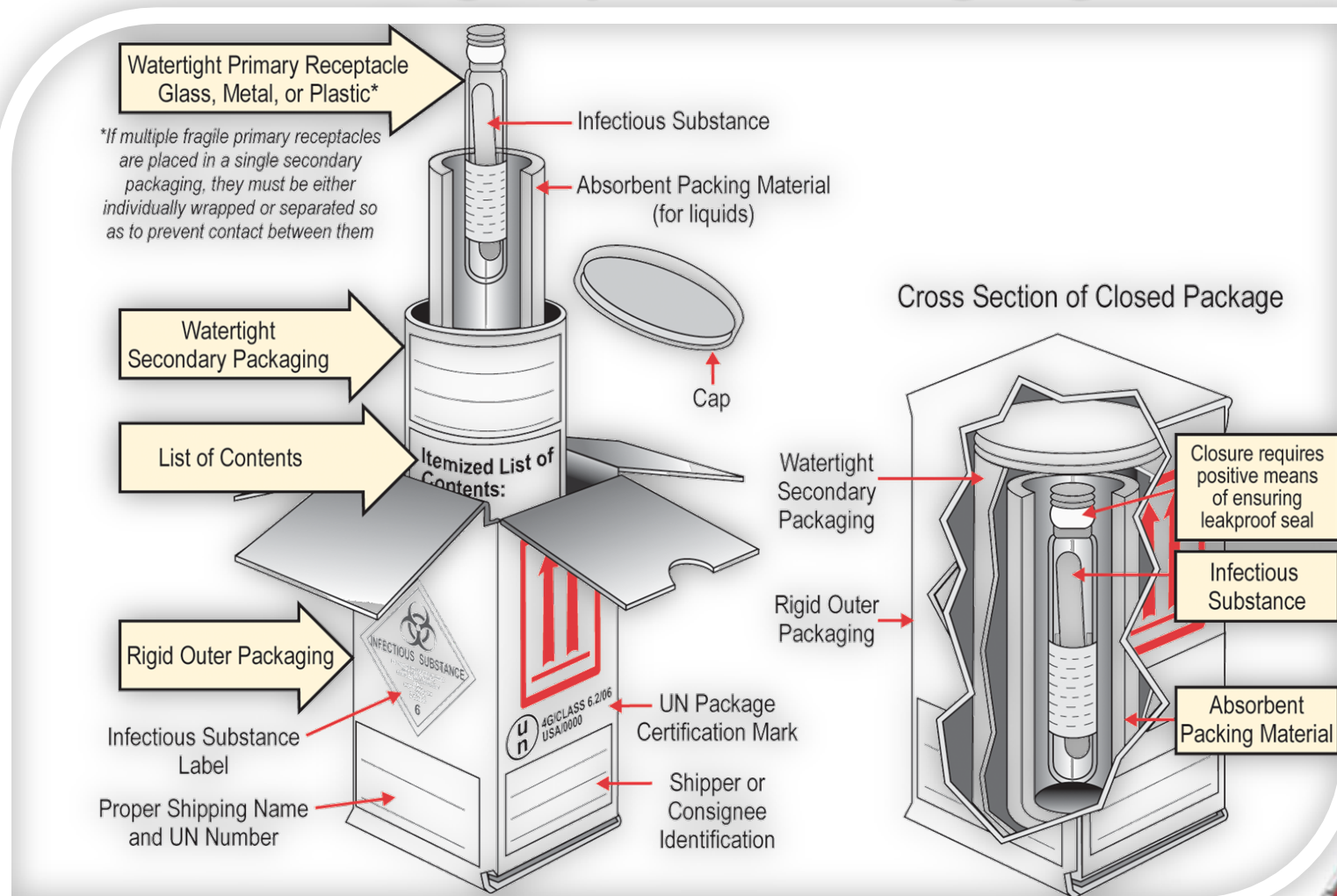
Packaging Requirements

173.24	General Packaging
173.24a	Requirements for all HAZMAT
173.24a(c)	Changes regarding Infectious Substances and mixed contents
173.134(b) 173.134(c)	Exceptions for: Division 6.2 Packaging Regulated Medical Waste
173.196	Category A Infectious Substance
173.197	Regulated Medical Waste
173.199	Category B Infectious Substance
178.609	6.2 Packaging Tests



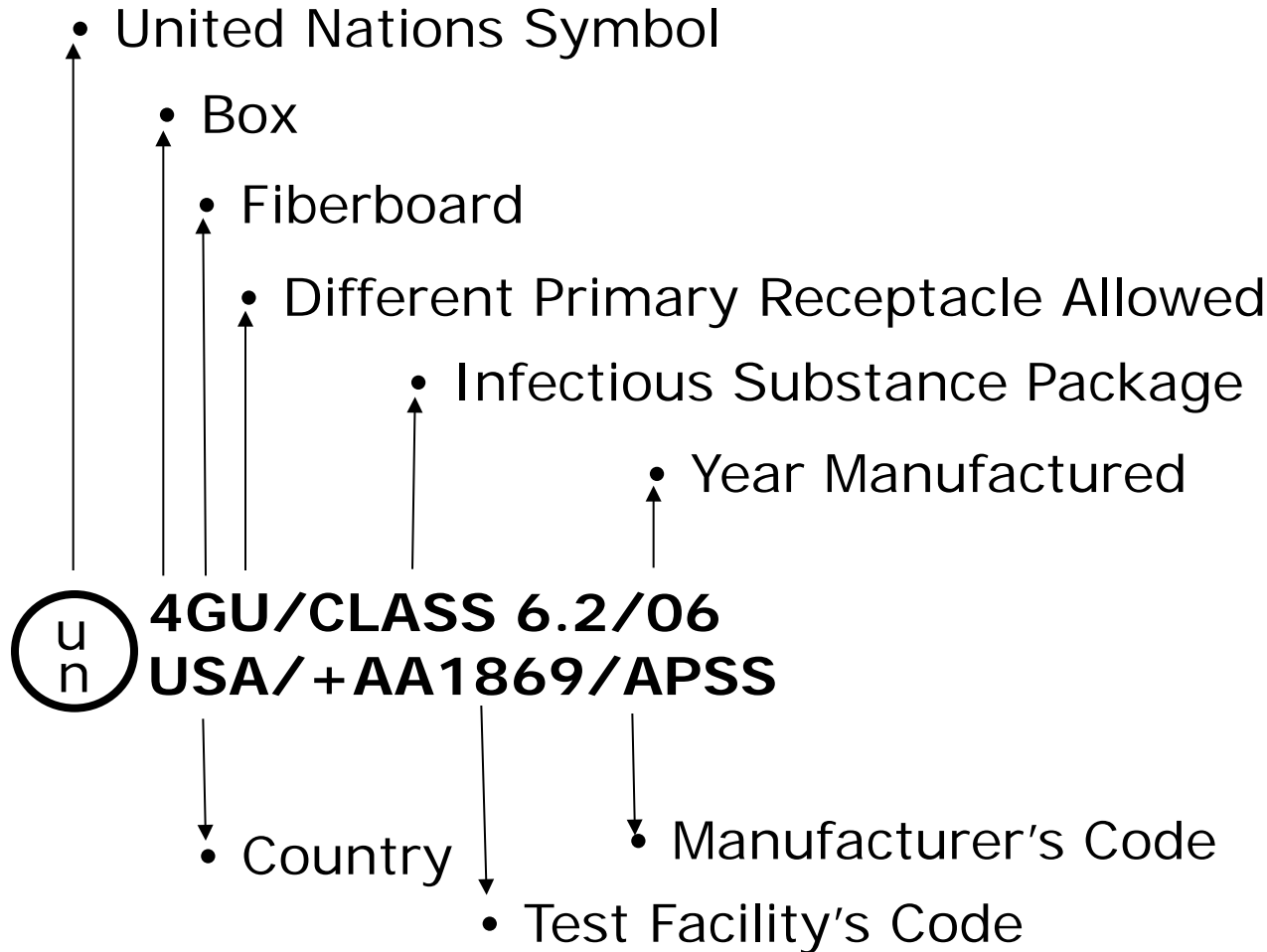


Category A Packaging



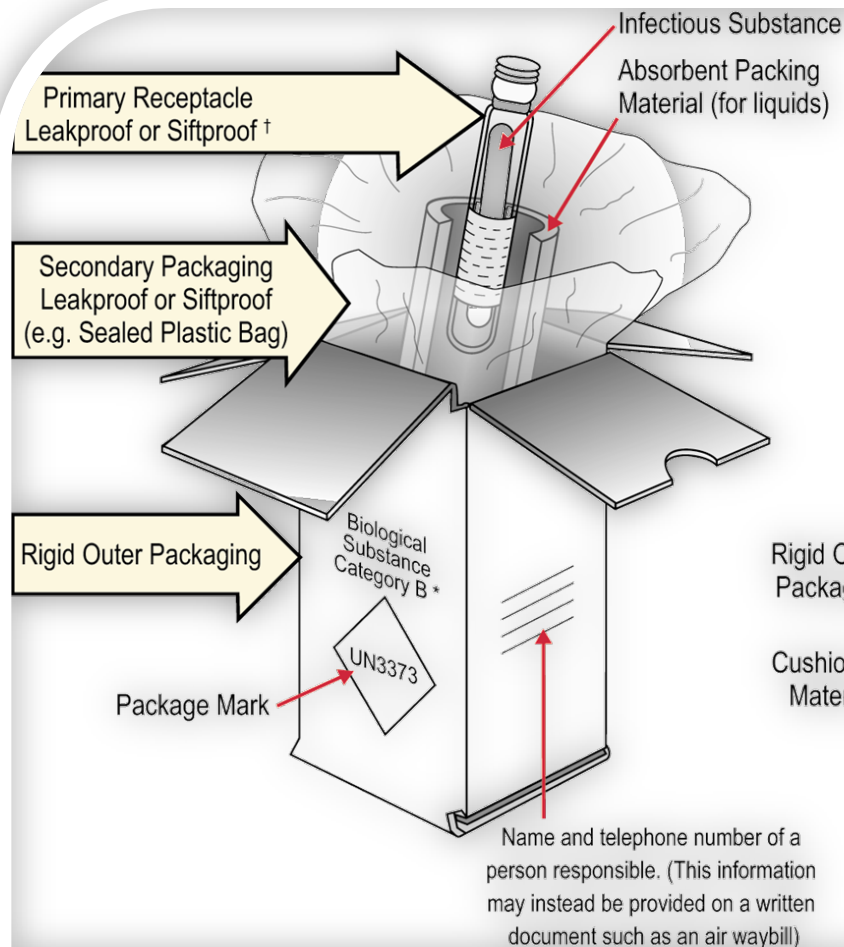


UN Packaging – Division 6.2 Category A

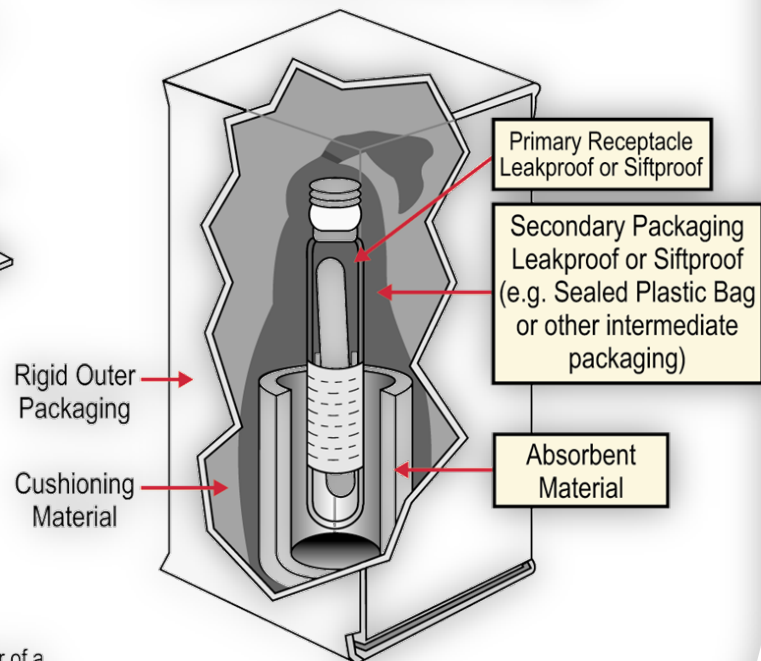




Category B Packaging



Cross Section of Closed Package





Used Health Care Products

- Products not conforming to CFR1910.1030 returned to manufacturer
- Triple non-spec package
- BIOHAZARD mark on primary and secondary packaging
- Itemized list
- No shipping paper, label, or emergency response information





Regulated Medical Waste (RMW) Packaging

- Rigid
- Leak resistant
- Impervious to moisture
- Burst, tear, and break resistant
- Puncture resistant for sharps
- Sealed to prevent leaks
- Meets UN PG II specs of Part 178





Regulated Medical Waste

- Bulk packaging
 - Large packaging (UN spec)
 - BOP (non-spec)
 - Biohazard Mark
 - CART – requires drop test at PG II level
- Inner packaging
 - Solids: plastic film bag (ASTM performance tests)
 - Liquids: rigid, general packaging requirements in Part 173
 - Sharps: puncture-resistant, PG II performance level if over 20 gallons; closure procedures





Regulated Medical Waste Exceptions

- Non-bulk RMW transported by private or contract carrier
 - No label if OSHA BIOHAZARD mark
 - Non-spec packaging and OSHA packaging
(other than waste concentrated stock culture of an infectious substance)
- Cultures/stocks in OSHA packaging and *vehicle used exclusively to transport RMW* (Category B infectious substance)





From Regulated to Non-Regulated

Once sterilized, regulated medical waste is no longer considered a Division 6.2 material



RMW entering autoclave unit





Marking Requirements

- Marking requirements for packages include:
 - Proper shipping name and technical name when applicable
 - Identification number
 - Consignee or consignor name and address
 - DOT Special Permit (if applicable)
 - Orientation arrows (if applicable)
 - Net quantity of dry ice (if applicable)





Proper Shipping Names and Identification Numbers

- Biological substance, Category B, UN3373
- Category A infectious substance:
 - Infectious substances, affecting animals, *only*, UN2900
 - Infectious substances, affecting humans, UN2814
- Regulated medical waste, n.o.s., UN3291





Marking Requirements



§ 173.4a(g)



§ 172.323(c)
& § 173.134(c)(1)(i)



§ 172.432
Label with "404" CDC number
expired 10/1/05



§ 173.199(a)(4)
Category B infectious substance



§ 172.302
Bulk Marking (can also be on
plain white placard)





Marking and Label Requirements

- **Category A**
 - Proper shipping name, UN 2814 or UN 2900 (as applicable)
 - Shipper or Consignee identification
 - Infectious Substance Label
 - Orientation arrows (as applicable)
- **Category B**
 - Proper shipping name
 - UN 3373 marking
 - Name and telephone number of responsible person
(may be placed on separate document such as air waybill)
 - Orientation arrows (as applicable)





Marking and Label Requirements (cont'd)

- **Regulated medical waste**
 - Proper shipping name
 - UN 3291
 - Consignor or Consignee name and address
 - Infectious substance label
 - Orientation arrows (as applicable)





Biological Substance, Category B Marking



UN3373

A large, empty diamond-shaped outline is centered on the slide, representing the shape of a standard hazard label. The text 'UN3373' is centered within this diamond.

49 CFR 173.199(a)(5)





Division 6.2 Label

- Required label for:
 - Category A Infectious Substance
 - Regulated Medical Waste (unless excepted)





Shipping Papers

- **Category A**
 - Identification Number
 - Proper Shipping Name
 - "suspected Category A infectious substance"
(technical name as applicable)
 - Hazard Class/Division
 - Packing Group
 - Total Quantity
 - Shipper's Certification
 - Emergency Response Telephone Number
- **Category B (unless excepted)**
 - No shipping papers required





Shipping Papers – Regulated Medical Waste

- Shipping description:
 - Proper Shipping Name
 - Hazard Class/Division
 - Identification Number
 - Packing Group
 - Total Quantity
 - Shipper's Certification
 - Emergency Response Telephone Number





Emergency Response Information

- Requirements for providing and maintaining emergency response information identified in Part 172, Subpart G
- May be on shipping paper or other document
- Exception: not required if a shipping paper is not required



Photo: Lawrence Berkeley National Lab





Division 6.2 Materials of Trade (MOTS)

- **Definition**
 - Hazmat on private motor carrier in direct support of principal business that is other than transportation
- **Examples:**
 - Home health care products, biological product or regulated medical waste





MOTS Exception

- A Division 6.2 other than Category A contained in human or animal samples transported as:
 - Research, diagnosis, investigation activities; or disease treatment or prevention, i.e.
 - Blood and its components
 - Tissue and tissue fluids
 - Body parts; or
 - Biological product
 - Regulated medical waste (RMW)





MOTS Exception (cont.)

- Non-spec combination packagings with quantity limits
- Aggregate gross weight of all MOTS on motor vehicle may not exceed 200 kg (440 lbs)





Other Requirements – Security Plan

- A security plan is required for:
 - Select agent or toxin regulated by CDC under 42 CFR part 73
 - By April 1, 2007 for select agent or toxin regulated by USDA under 9 CFR part 121
- The plan must include:
 - Assessment of security risks
 - Address personnel security, unauthorized access, and en route security



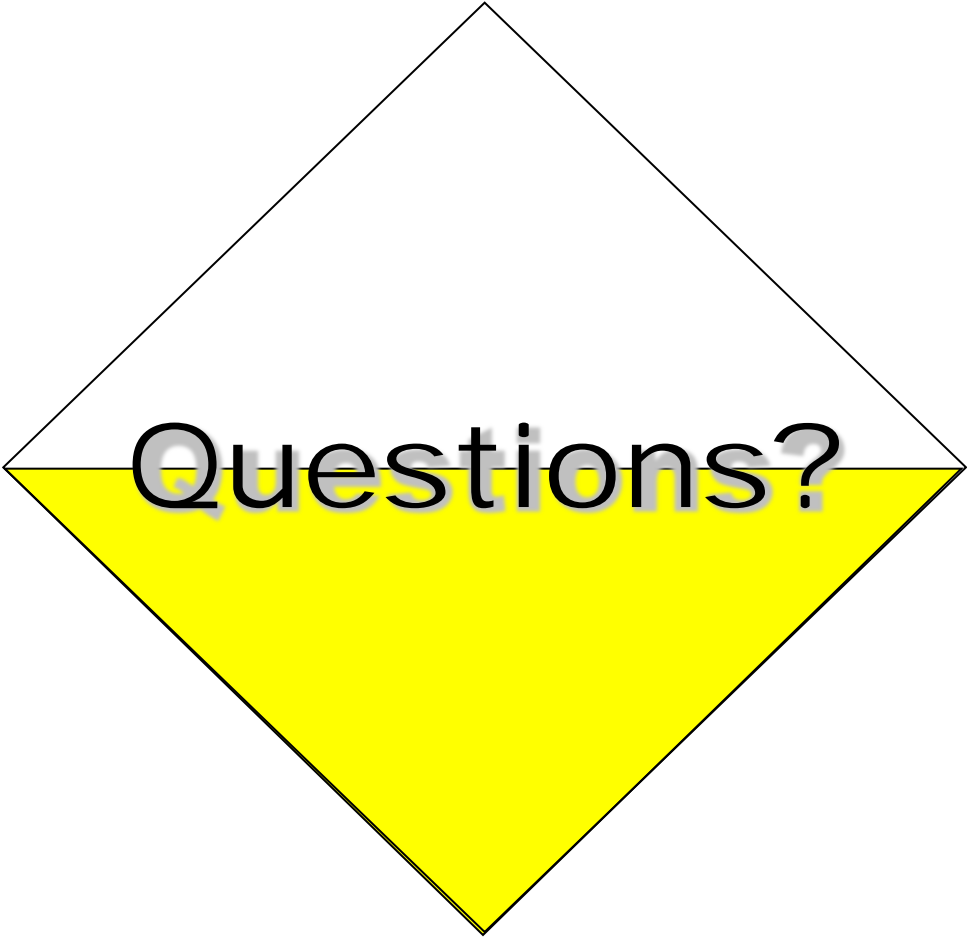


Other Requirements – Training

- Federal hazardous materials transportation law 49 CFR, Part 172, Subpart H, requires training of *all* hazmat employees. Training must include:
 - General Awareness / Familiarization
 - Safety
 - Function Specific
 - Security Awareness
 - In-depth Security (when applicable)
- Anyone shipping infectious substances must have “knowledge and training”

49 CFR 172.704(a); 173.134(b); 173.199(e)







Where to Find More Information...

The screenshot shows the PHMSA website interface. At the top, the PHMSA logo and name are displayed, along with the U.S. Department of Transportation logo and navigation links for Contact Us, FAQs, and Site Map. Below the header, there are tabs for PHMSA Home, Pipeline Safety, and Hazardous Materials Safety. A search bar with a 'Go' button and 'Advanced Search' link is also present. The main content area features a large banner for the '2012 EMERGENCY RESPONSE GUIDEBOOK' with the headline 'DOT Distributes Over 2 Million New Hazardous Materials Emergency Guidebooks to Nation's First Responders'. To the right, there are sections for 'Hazmat News' and 'Most Viewed Info', both containing a list of links to various reports and updates. Below the banner, there is a 'Find PHMSA Offices' section with a dropdown menu for 'Key Officials' and 'Regional Offices', and a map of the United States showing regional offices. To the right of the map, there is a 'PHMSA/Hazmat Resources' section with links to 'Regulations & Rulemakings', 'Data & Reports', and 'Permits & Approvals'.

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A Guidebook for First Responders During the Initial Phase of a Dangerous Goods Transportation Incident

DOT Distributes Over 2 Million New Hazardous Materials Emergency Guidebooks to Nation's First Responders

1 2 3 4 5

Hazmat News | **Most Viewed Info**

Safety Advisories

- > [PHMSA Continues Push to Clarify & Update Hazmat Rules](#)
- > [2011 Hazmat Penalty Action Report](#)
- > [Hazmat Harmonization Rule on Air Packaging Issued](#)
- > [PHMSA seeks comment on transportation of lithium batteries](#)
- > [PHMSA Proposes Updating Hazmat Rules to Better Balance Safety Standards and Regulatory Requirements](#)

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PHMSA/Hazmat Resources

Regulations & Rulemakings
PHMSA regulates and ensures the safe movement of hazardous materials.

Data & Reports
PHMSA tracks data on the frequency of failures, incidents and accidents.

Permits & Approvals

<http://hazmat.dot.gov>





Hazardous Material Info-Center

1-800-HMR-4922

(1-800-467-4922)

E-mail: infocntr@dot.gov

Hours of Operation: 9 am – 5 pm ET



- Obtain answers to HMR questions
- Request copies of Federal Register, special permits or training materials
- Report HMR violations
- Fax on Demand





William Stevens Investigator

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